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Mary-Ellen M. Devlin
BOEHRINGER INGELHEIM
PHARMACEUTICALS INC.
900 Ridgebury Rd., P.O. Box 368
Ridgefield CT 06877-0368

Re: Patent Term Extension
Application for
U.S. Patent No. 5,216,167

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,216,167, which claims the human drug product PRANDIN™ (repaglinide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 921 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods. In the absence of such request for reconsideration or election of U.S. Patent No. 5,312,924, the Commissioner will issue a certificate of extension, under seal, for a period of 921 days in the above-identified patent.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 28, 1999 (64 Fed. Reg. 4425). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,916 - 424) + 175
= 921 days

Since the regulatory review period began April 3, 1992, before the patent issued (June 1, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From April 3, 1992 to June 1, 1993 is 424 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

It is noted that applicant has also filed an application for patent term extension of U.S. Patent No. 5,312,167 based upon the regulatory review of PRANDIN™. No more than one patent may be extended for a single regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different eligible patents based upon the same regulatory review period for a product, the certificate of extension is issued to the eligible patent having the earliest date of issuance unless applicant elects a different eligible patent. Therefore, only one of above-identified patent and U.S. Patent No. 5,312,924 can be extended based upon the regulatory review period of PRANDIN™ and applicant should elect the patent to be extended. Unless applicant elects another patent within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be granted based upon the regulatory review period of PRANDIN™. Extension of time under 37 CFR 1.136(a) is NOT permitted. Upon issuance of the certificate of extension, the

following information will be published in the Official Gazette:

U.S. Patent No.:	5,216,167[1]
Granted:	June 1, 1993
Original Expiration Date[2]:	October 10, 2006
Applicant:	Wolfgang Grell et al.
Owner of Record:	Dr. Karl Thomae GmbH
Title:	Phenylacetic Acid Benzylamides
Classification:	546/234
Product Trade Name:	PRANDIN™ (repaglinide)
Term Extended:	921 days
Expiration Date:	April 18, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor, Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: PRANDIN™ (repaglinide)
FDA Docket No.: 98E-0616

[1]It is noted that reissue application No. 08/946,602 has been allowed.

[2]Subject to the provisions of 35 U.S.C. § 41(b).